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KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER SHAW, AMANDA MARIE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,188

Applicant(s)

GORMLEY ET AL.

Examiner

Amanda Shaw

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 27-36 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 4 and 27-36 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 6/2/2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the amendment filed May 4, 2009. This action is made FINAL.

Claims 4 and 27-36 are currently pending. Claims 4, 27, 30, 32, and 33 have been amended. Claims 34-36 are newly presented.

Withdrawn Objections

2. The objection made to claim 4 in section 4 of the Office Action of January 28, 2009 is withdrawn in view of the amendment made to the claim.

Withdrawn Rejections

3. The rejections made under 35 USC 112 2nd paragraph in section 5 of the Office Action of January 28, 2009 are withdrawn in view of amendments made to the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejections have been modified based on the applicant's amendments:

5. Claims 4, 27-28, 30-31, 33, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanisan (WO 01/57248 Pub 9/2001) as evidenced by Cheeseman (US Patent 5302509 Issued 1994) in view of Soper (US Patent 5846727) and Parker (US Patent 5565323)

Regarding Claims 4, 35, and 36 Balasubramanisan teaches a method comprising forming an array of polynucleotide molecules immobilized on a solid surface. Each polynucleotide has a hairpin loop structure wherein one end of hairpin loop structure acts as a primer and the other end of the hairpin loop structure acts as a template (page 3, lines 11-14 and page 4 line 28 to page 5 line 7). Balasubramanisan further teaches that the polynucleotides are attached to the array at a density of between 10^6 - 10^9 sequences per cm^2 (page 4, line 9). Balasubramanisan also teaches determining the sequence of the template nucleic acids by synthesizing a complementary nucleic acid strand. Specifically Balasubramanisan cites the method of Cheeseman as a suitable sequencing method (page 7, lines 24-31). The method of Cheeseman comprises

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contacting the template with fluorescently labeled 3' blocked nucleotide triphosphates, with each of the bases having a different fluorescent label and a polymerase. The DNA polymerase causes selective addition of only the complementary labeled NTP, thus identifying the next unpaired base in the unknown strand. The 3' blocking group is then removed, setting the system up for the next NTP addition and so on (Abstract). Thus Balasubramanisan as evidenced by Cheeseman teaches determining the sequence of the template nucleic acids by synthesizing a first complementary copy of each of the template sequences wherein said synthesizing involves repeated cycles of incorporating a single nucleotide into the first complementary copy and detecting incorporation of the single nucleotide thereby performing a first round of sequencing. Regarding Claims 27 and 28 Balasubramanisan teaches a method wherein the template polynucleotides are attached to a double stranded anchor wherein the double stranded anchor is a complementary hairpin (page 4 line 28 to page 5 line 7). Regarding Claim 30 Balasubramanisan teaches that the templates are individually resolvable (page 4, line 11). Regarding Claim 31 Balasubramanisan teaches a method wherein the sequencing determination is carried out using cycles of incorporation and detection of fluorescently labeled nucleotides. Specifically Balasubramanisan refers to the method of Cheeseman which teaches this (see Cheeseman abstract). Regarding Claim 33 Balasubramanisan teaches a method which employs a polymerase enzyme to synthesize a complementary strand one base at a time. Specifically Balasubramanisan cites the method of Cheeseman which teaches using Taq polymerase (see Cheeseman Col 3, line 67). Further regarding claim 35 the recitation of "a method for simultaneously sequencing a

complete genome" is not accorded any patentable weight because it merely recites the intended use of the method.

Balasubramanisan does not teach a method further comprising removing the complementary copy of each of the template sequences and performing a second round of sequencing (clms 4, 35, and 36).

However Soper teaches a sequencing method wherein after primer extension the extension products are removed from the immobilized templates by denaturing with mild aqueous alkali. Soper then teaches that after the extension products have been removed the biotinylated template is ready for "resequencing" if desired (Col 8, lines 54-61). Thus Soper teaches a method further comprising removing the complementary copy of the template sequence and performing a second round of sequencing.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Balasubramanisan by removing the complementary strand as suggested by Soper and resequencing the template as suggested by Soper using the sequencing method of Balasubramanisan. One of skill in the art would have been motivated to remove the complementary strand and resequence the template in order to verify the nucleotide sequence. Further the rationale to support a conclusion that the claims would have been obvious is that all of the claimed method steps were known in the prior art and one skilled in the art could have arrived at the claimed invention by combining the steps that were taught in the prior art. From the teachings of the references, it was apparent that one of ordinary skill

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in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

The combined teachings of Balasubramanish and Soper do not teach comparing the sequence of the first complementary copy to the sequence of the second complementary copy for each of the immobilized single stranded template nucleic acid molecules to confirm sequencing data of each of the immobilized single stranded template nucleic acid molecules (clms 4, 35, and 36). Further the combined references do not teach a method wherein the comparing step reduces random sequencing errors of the template sequences arising from the first round of sequencing (clm 34).

However Parker teaches a method wherein multiple sequences are obtained and then the sequences are aligned and compared with published sequences. Mutations were noted and then confirmed by resequencing the variant regions (col 15, lines 50-54). Thus Parker teaches comparing multiple sequences to confirm sequencing data. Since the mutations that were noted were confirmed by resequencing the method of Parker is being interpreted as a method that reduces random sequencing errors of the template sequences arising from the first round of sequencing.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Balasubramanish and Soper by comparing the sequence of the first complementary copy to the

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sequence of the second complementary copy for each of the immobilized single stranded template nucleic acid molecules to confirm sequencing data of each of the immobilized single stranded template nucleic acid molecules as suggested by Parker. It would have been obvious to one of skill in the art to compare the obtained sequences in order to confirm that the obtained sequences were identical. Further the rationale to support a conclusion that the claims would have been obvious is that all of the claimed method steps were known in the prior art and one skilled in the art could have arrived at the claimed invention by combining the steps that were taught in the prior art. Further one of skill in the art would have had a reasonable expectation of success in doing so.

The following rejection was previously presented:

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanish (WO 01/57248 Pub 9/2001) as evidenced by Cheeseman (US Patent 5302509 Issued 1994) in view of Soper (US Patent 5846727) and Parker (US Patent 5565323) as applied to claims 4 and 27 above and in further view of Lackey (US Patent 5652126).

The teachings of Balasubramanish (evidenced by Cheeseman), Soper, and Parker are presented above.

The combined references do not teach a method wherein the double stranded anchor (which acts as a primer) comprises a recognition site for a restriction endonuclease.

However Lackey teaches a method that comprises synthesizing a complementary copy nucleic acid sequence using a template sequence. Lackey further teaches when a DNA primer/template with a single 3' ribonucleotide is used, cleavage at the ribonucleotide residue, followed by separation and purification of the oligonucleotide product, results in a fully regenerated and reusable primer/template (Col 13, lines 26-31). Lackey further teaches that cleavage may be performed using a site specific restriction endonuclease, alkaline hydrolysis or an endonuclease such as RNase (col 12, lines 42-47). Thus Lackey teaches a method wherein the primer has a recognition site for a restriction endonuclease.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Balasubramanisan, Soper, and Parker by using a double stranded anchor (that acts as a primer) that comprises a recognition site for a restriction endonuclease. The use of such a double stranded anchor would be beneficial because primer extension products could easily be removed by using a restriction endonuclease that cuts at the recognition site thereby allowing the template and the primer to be reused. Since all of the claimed method steps were known in the art, one of skill could have combined these methods and the combination would have yielded predictable results.

The following rejection was previously rejected:

7. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanisan (WO 01/57248 Pub 9/2001) as evidenced by Cheeseman (US Patent

5302509 Issued 1994) in view of Soper (US Patent 5846727) and Parker (US Patent 5565323) as applied to claims 4 and 31 above and in further view of Barnes (WO 01/57249 Pub 8/2001).

The teachings of Balasubramanish (evidenced by Cheeseman), Soper, and Parker are presented above.

The combined references do not teach a method wherein the fluorescent nucleotides are detected using a microscope with total internal reflection based imaging.

However Barnes teaches that using total internal reflection fluorescent microscopy it is possible to achieve wide field imaging with single polymer sensitivity. This allows arrays of greater than 10^7 resolvable polymers per cm^2 to be used (page 6, lines 9-14).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Balasubramanish, Soper, and Parker by using a microscope with total internal reflection to detect the incorporation of each nucleotide as suggested by Barnes particularly since Barnes teaches it is possible to achieve wide field imaging with single polymer sensitivity and that this allows arrays of greater than 10^7 resolvable polymers per cm^2 to be used. Therefore it would have been obvious to use the detection method disclosed by Barnes for the benefit of being able to detect a large number of individual fluorescent nucleotides present on the array.

Response To Arguments

8. In the response filed May 4, 2009, Applicants traversed the rejection over Balasubramanian (WO 01/57248 Pub 9/2001) in view of Soper (US Patent 5846727) and Parker (US Patent 5565323) as evidenced by Cheeseman (US Patent 5302509 Issued 1994).

The Applicants state that while Soper teaches what is missing in Balasubramanian Soper fails to provide any motivation as to what circumstances would render resequencing desirable. Absent such instructive guidance, applicants argue that it is not apparent what conditions would motivate an ordinarily skilled practitioner to resequence a template. Then the applicants go on to argue that the sequencing method of Soper differs substantially from the sequencing method of Balasubramanian (as evidenced by Cheeseman). Based on the lack of common method steps, Applicants assert that an ordinarily skilled practitioner would have had no reason to combine the method of Balasubramanian with the method of Soper to arrive at the present method. They further state that the previous office action has failed to provide a rationale to support the contention that it would allegedly have been obvious for an ordinarily skilled practitioner to combine the incongruent methods of Balasubramanian and Soper to arrive at the present invention. Further applicants state that a gel based sequencing method such as that described by Soper cannot be used to determine "... the sequences of the immobilized single stranded template nucleic acid molecules by synthesizing a first complementary copy of each of the template sequences, wherein said synthesizing involves repeated cycles of incorporating a single nucleotide into the

first complementary copy and detecting incorporation of the single nucleotide, ..." as recited in the instant claims.

These arguments have been fully considered but are not persuasive. KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>). However motivation is present and has been provided. One of skill in the art would have been motivated to remove the complementary strand and resequence the template in order to verify the nucleotide sequence. It was well known in the art at the time of the invention that sequencing errors could occur therefore it would be desirable to verify any nucleic acid sequence by resequencing. Further the rationale to support a conclusion that the claims would have been obvious is that all of the claimed method steps were known in the prior art and one skilled in the art could have arrived at the claimed invention by combining the steps that were taught in the prior art. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references. Additionally it is noted that the test for obviousness is not whether two methods have steps in common with one another. In the instant case both of the references being relied upon are drawn to methods for nucleic acid sequencing and therefore one of skill in the art

would have a reason to combine the method of Balasubramanian with the method of Soper to arrive at the present method. As clarified in the rejection above Soper is only being relied upon to teach what is missing in Balasubramanian i.e., the step of removing the complementary copy of each of the template sequences and performing a second round of sequencing (wherein the resequencing is being performed using the sequencing method of Balasubramanian). Therefore the fact that the gel based method of Soper can not be used to determine the sequences of the immobilized single stranded template nucleic acid molecules by synthesizing a first complementary copy of each of the template sequences, wherein said synthesizing involves repeated cycles of incorporating a single nucleotide into the first complementary copy and detecting incorporation of the single nucleotide is irrelevant because Balasubramanian teaches a sequencing method that meets this limitation. The rejection does not suggest that the "resequencing" should be performed using the sequencing methodology of Soper.

The applicant's further state that the instant method calls for comparing the sequences of the first and second complementary copies of each of the templates immobilized on the array to confirm sequencing data of each of the immobilized single stranded template nucleic acid molecules. With regard to this limitation the applicants argue that Parker does not cure the defects of Balasubramanian and Soper. They argue that the gel based sequencing methods of Soper and Parker could not be used in a way to "confirm sequencing data of each of the immobilized single-stranded template nucleic acid molecules" as recited in the claims. Further they state that there is no motivation.

These arguments have been fully considered but are not persuasive. It is reiterated that KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>). However motivation is present and has been provided. One of skill in the art would have been motivated to compare the obtained sequences in order to confirm that the obtained sequences were identical (that they did not have any sequencing errors). It was well known in the art at the time of the invention that sequencing errors could occur therefore it would be desirable to compare the obtained sequences to verify that they were error free. Further the rationale to support a conclusion that the claims would have been obvious is that all of the claimed method steps were known in the prior art and one skilled in the art could have arrived at the claimed invention by combining the steps that were taught in the prior art. Further one of skill in the art would have had a reasonable expectation of success in doing so. Additionally it is noted that Soper and Parker are only being relied upon to teach what is missing in Balasubramanian. As clarified in the rejection above Soper is only being relied upon to teach the step of removing the complementary copy of each of the template sequences and performing a second round of sequencing (wherein the resequencing is being performed using the sequencing method of Balasubramanian) and Parker is only being relied upon to teach the step of comparing the sequence of the first complementary copy to the sequence of the second

complementary copy to confirm sequencing data. Therefore the fact that the gel based methods of Soper and Parker can not be used to determine the sequences of the immobilized single stranded template nucleic acid molecules by synthesizing a first complementary copy of each of the template sequences, wherein said synthesizing involves repeated cycles of incorporating a single nucleotide into the first complementary copy and detecting incorporation of the single nucleotide is irrelevant because Balasubramanian teaches a sequencing method that meets this limitation. The rejection does not suggest that the "resequencing" should be performed using the sequencing methodology of Soper or Parker.

Additionally the Applicants traversed the rejection over Balasubramanian (WO 01/57248 Pub 9/2001) in view of Soper (US Patent 5846727) and Parker (US Patent 5565323) and evidenced by Cheeseman (US Patent 5302509 Issued 1994) as applied to claims 4 and 27 above and further in view of Lackey et al. (USPN 5,652,126). The Applicants restate that the previous Office Action has failed to provide sufficient evidence to support the contention that an ordinarily skilled artisan would have had any motivation to combine the teachings of Balasubramanian, Cheeseman, Soper, and Parker to arrive at the instantly claimed methods. They further state that Lackey has nothing to do with sequencing. Therefore there is no motivation to use Lackey.

These arguments have been fully considered but are not persuasive. The applicant's arguments regarding the combination of Balasubramanian, Cheeseman, Soper, and Parker have been fully addressed above. The response to applicant's arguments as set forth above applied equally to the present grounds of rejection. While

Lackey may not be directed to "sequencing" per se, Lackey is not being relied upon to teach "sequencing" because it is taught by Balasubramanian. The method of Lackey is relevant to the instant claims because the method comprises synthesizing a complementary nucleic acid sequence using a template sequence which is also required by the instant claims. Lackey is only being relied upon for teaching a method which uses a primer that has a recognition site for a restriction enzyme wherein in the presence of a restriction enzyme cleavage occurs which results in a fully regenerated and reusable primer/template. Based on the teachings of Lackey it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Balasubramanian, Soper, and Parker by using a double stranded anchor (that acts as a primer) that comprises a recognition site for a restriction endonuclease. The use of such a double stranded anchor that comprises a recognition site for a restriction endonuclease would be beneficial because primer extension products could easily be removed by using a restriction endonuclease that cuts at the recognition site thereby allowing the template and the primer to be reused. Thus motivation to combine the methods of Balasubramanian, Cheeseman, Soper, and Parker with Lackey is present and has been provided.

Additionally the Applicants traversed the rejection over Balasubramanian (WO 01/57248 Pub 9/2001) in view of Soper (US Patent 5846727) and Parker (US Patent 5565323) and evidenced by Cheeseman (US Patent 5302509 Issued 1994) as applied to claims 4 and 31 above and further in view of Barnes (WO 01/57249; published 8/2001). The Applicants restate that the previous Office Action has failed to provide

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sufficient evidence to support the contention that an ordinarily skilled artisan would have had any motivation to combine the teachings of Balasubramanian et al., Cheeseman, Soper et al., and Parker et al. to arrive at the instantly claimed methods. They further state that Barnes does not cure this deficiency.

These arguments have been fully considered but are not persuasive. The applicant's arguments regarding the combination of Balasubramanian, Cheeseman, Soper, and Parker have been fully addressed above. The response to applicant's arguments as set forth above applied equally to the present grounds of rejection. Based on the references, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Balasubramanian, Cheeseman Soper, and Parker by using a microscope with total internal reflection to detect the incorporation of each nucleotide as suggested by Barnes particularly since Barnes teaches it is possible to achieve wide field imaging with single polymer sensitivity and that this allows arrays of greater than 10^7 resolvable polymers per cm^2 to be used. Therefore it would have been obvious to use the detection method disclosed by Barnes for the benefit of being able to detect a large number of individual fluorescent nucleotides present on the array. As such motivation is present and has been provided.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

/Carla Myers/
Primary Examiner, Art Unit 1634